



10018899.06 Date 12-17-2001 JC07 Rec'd PCT/PTO 17 DEC 2001

FORM PTO-1390
(REV. 9-2001)

U.S. DEPARTMENT OF COMMERCE

U.S. Patent & TMO/TM Mail Rcpt Dt. #26

ATTORNEY'S DOCKET NUMBER

MALCC 59155

**TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371**

U.S. APPLICATION NO. (If known, see 37 CFR 1.53)

10/018899

INTERNATIONAL APPLICATION NO
PCT/US00/06164

INTERNATIONAL FILING DATE
9 March 2000

PRIORITY DATE CLAIMED
12 March 1999

TITLE OF INVENTION

FACE OR NOSE MASK FOR NON-INVASIVE VENTILATION OF PATIENTS IN GENERAL

APPLICANT(S) FOR DO/EO/US

FINI, Massimo, et al.

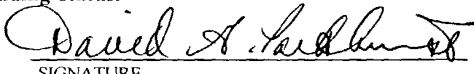
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31)
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☒ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ has been communicated by the International Bureau
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. ☐ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau)
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A **FIRST** preliminary amendment.
14. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information: **Return Postcard, Petition to Revoke, Check (\$1,280.00)**

10018899 060602
531 Rec'd PCT 17 DEC 2001

U.S. APPLICATION NO. <u>10/018899</u> PCT/US00/06164 INTERNATIONAL APPLICATION NO.				ATTORNEY'S DOCKET NUMBER <u>MALCC 59155</u>	
21. <input checked="" type="checkbox"/> The following fees are submitted: BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)): Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO. \$1040.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO \$890.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$740.00 International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$710.00 International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) \$100.00 ENTER APPROPRIATE BASIC FEE AMOUNT =				CALCULATIONS PTO USE ONLY <div style="border-top: 1px solid black; border-bottom: 1px solid black; padding: 2px 0;">\$ 710.00</div>	
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				<div style="border-top: 1px solid black; border-bottom: 1px solid black; padding: 2px 0;">\$ 130.00</div>	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	5 - 20 =	-0-	x \$18.00		
Independent claims	4 - 3 =	1	x \$84.00	\$ 84.00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$280.00		
TOTAL OF ABOVE CALCULATIONS =				\$ 924.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$	
SUBTOTAL =				\$ 924.00	
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$	
TOTAL NATIONAL FEE =				\$ 924.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)) The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$	
TOTAL FEES ENCLOSED =				\$ 924.00	
				Amount to be refunded:	\$
				charged:	\$
a. <input checked="" type="checkbox"/> A check in the amount of \$ <u>924.00</u> to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>06-2425</u> . A duplicate copy of this sheet is enclosed. d. <input type="checkbox"/> Fees are to be charged to a credit card WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.					
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.					
SEND ALL CORRESPONDENCE TO: David G. Parkhurst, Esq. FULWIDER PATTON LEE & UTECHT, LLP Howard Hughes Center 6060 Center Drive - 10th Fl. Los Angeles, CA 90045				<div style="text-align: center;">  SIGNATURE David G. Parkhurst NAME <u>29,422</u> REGISTRATION NUMBER December 17, 2001 </div>	

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MALCC 59155

FROM

FULWIDER • PATTON
FULWIDER PATTON LEE & UTECHT, LLP
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TO

BOX PCT
Commissioner for Patents
Washington, D.C. 20231

JC15 Rec'd PCT/PTO 12 APR 2002

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APR 17 2002
INITIAL PROCESSING

668,810/01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:) Examiner: Not assigned
)
FINI, Massimo, et al.) Group Art Unit: Not assigned
)
U.S. Serial No.: Unassigned) Docket No. MALCC 59155
)
PCT International Application No.:)
PCT/US00/06164)
) Los Angeles, California 90045
Int'l Filing Date: 9 March 2000) Date: December 17, 2001
)
For: FACE OR NOSE MASK FOR)
NON-INVASIVE VENTILATION OF) Express Mail No.: EL737666670 US
PATIENTS IN GENERAL)

PRELIMINARY AMENDMENT

BOX PCT
Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

This Preliminary Amendment is being filed concurrently with the National Phase PCT Application for Letters Patent.

Entry of the following amendments prior to examination of the application is respectfully requested.

Docket No. MALCC 59155

IN THE CLAIMS:

Please amend the claims as follows:

3. (Amended) The mask according to claim 1, wherein said first and second chambers lie side by side, one inside the other.

4. (Amended) The mask according to claim 1, wherein said first and second chambers are alternately connected to said pressurized air source.

5. (Amended) The mask according to claim 1, wherein said pressurized air source is constituted by micropumps, each of which is connected to the corresponding chamber.

Docket No. MALCC 59155

REMARKS

In light of the foregoing amendments, favorable consideration of the application is respectfully requested.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP



David G. Parkhurst
Registration No. 29,422

DGP/rvw

Encls.: Version With Markings To Show Changes Made
 Return Postcard

Howard Hughes Center
6060 Center Drive, Tenth Floor
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Tele. No. (310) 824-5555
Facsimile No. (310) 824-9696

Customer No. 24201

VERSION WITH MARKINGS TO SHOW CHANGES MADE

3. (Amended) The mask according to [the preceding claims, characterized in that] claim 1, wherein said first and second chambers lie side by side, one inside the other.

4. (Amended) The mask according to [one or more of the preceding claims, characterized in that] claim 1, wherein said first and second chambers are alternately connected to said pressurized air source.

5. (Amended) The mask according to [one or more of the preceding claims, characterized in that] claim 1, wherein said pressurized air source is constituted by micropumps, each of which is connected to the corresponding chamber.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#5

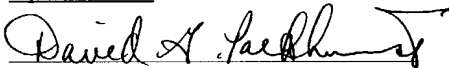
In re application of:

Massimo Fini, et al.

U.S. Serial No.: 10/018,899

PCT International Application No.:
PCT/US00/06164

Int'l Filing Date: 9 March 2000

For: FACE OR NOSE MASK FOR
NON-INVASIVE VENTILATION OF
PATIENTS IN GENERAL) Examiner: Not assigned
) Group Art Unit: Not assigned
) Docket No. MALCC 59155
)**CERTIFICATE OF MAILING**) I hereby certify that this paper and the documents referred
) to as being attached or enclosed herewith are being
) deposited with sufficient postage as First Class Mail in an
) envelope addressed to: **Box PCT, COMMISSIONER**
) **FOR PATENTS, WASHINGTON, D.C. 20231** on
) April 3, 2002.) 
) David G. Parkhurst, Reg. No. 29,422

April 3, 2002

Los Angeles, California 90045

SUPPLEMENTAL PRELIMINARY AMENDMENTBOX PCT
Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

This Preliminary Amendment is supplemental to the Preliminary
Amendment dated December 17, 2001.

Entry of the following amendment prior to examination of the application
is respectfully requested.

IN THE SPECIFICATION:

Please amend the Specification at page 1, after the title, and before line 3 to insert
the following paragraph:

U.S. Serial No. 10/018,899

RELATED APPLICATIONS:

This application claims priority from PCT International Application No. PCT/US00/06164, having the international filing date of 9 March 2000, and Italian Application No. MI 99A000521, filed March 12, 1999.

REMARKS

The foregoing amendment revises the Specification to contain a reference to the prior international application and the Italian national application from which priority are claimed.

Favorable consideration of the application is respectfully requested.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP



David G. Parkhurst
Registration No. 29,422

DGP/blh
Enclosure: Return Postcard

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Customer No. 24201

FACE OR NOSE MASK FOR NON-INVASIVE VENTILATION OF PATIENTS IN GENERAL

The present invention relates to a face or nose mask for non-invasive ventilation of patients in general.

5 It is known that the main problem in long-term ventilation performed by means of a mask is the tolerability of the mask by the patient.

One of the most unpleasant and harmful effects arises from the compression of the skin that is produced by the sealing element provided in the perimetric region of the mask, which is pressed against the user's face;
10 this effect is particularly damaging at the upper nasal region.

The pressure applied by the mask in fact reduces blood flow in the affected part of the skin and in the long term causes pain and sores may form in the region.

In order to try to at least partially solve this problem, masks have already
15 been provided in which the sealing element is formed in practice by an air-filled chamber or air cushion which, in order to reduce the period of contact with the skin, is in practice deflated at least at the upper part of the nasal septum during expiration, a step in which there is no need to provide a seal since the patient is expelling air. The chamber is then instantly reinflated
20 during inspiration, thus forming a seal again and in practice reducing the time of contact between the skin and the inflatable chamber.

Also this solution has not proved to be particularly effective, since the inflation and deflation rate is closely dependent on the ratio between the expiration phase and the inspiration phase and because a relatively high
25 residual pressure always remains and is applied by the mask to the skin.

The aim of the present invention is to eliminate the above-noted drawbacks, by providing a face or nose mask for non-invasive ventilation of patients in general which allows to reduce the time for which the pressure produced by the sealing element of the mask is applied, so that the above-
30 mentioned problems do not occur since blood flow in the affected skin

portion is possible at all times.

Within the scope of this aim, a particular object of the present invention is to provide a face or nose mask in which the perfect seal of the mask with respect to the outside is ensured at all times but the region where pressure is applied to the skin changes continuously.

Another object of the present invention is to provide a mask in which the system for inflating the sealing element is independent of the ventilation system, consequently allowing a wide range of adjustment for the pressure values used.

Another object of the present invention is to provide a mask which, by way of its particular constructive characteristics, is capable of giving the greatest assurances of reliability and safety in use.

Another object of the present invention is to provide a face or nose mask for non-invasive ventilation of patients in general which can be easily obtained starting from commonly commercially available elements and materials and is also competitive from a purely economical point of view.

This aim, these objects and others which will become apparent hereinafter are achieved by a face or nose mask for non-invasive ventilation of patients in general, according to the invention, which comprises a mask body provided with an inlet for connection to a ventilation apparatus and perimetrically provided with a sealing element for application to the face of a patient, characterized in that said sealing element comprises at least one first chamber and at least one second chamber which can be connected separately to a source of pressurized air.

Further characteristics and advantages of the present invention will become apparent from the following detailed description of a preferred but not exclusive embodiment of a face or nose mask for non-invasive ventilation of patients in general, illustrated only by way of non-limitative example in the accompanying drawings, wherein:

Figure 1 is a partially sectional schematic view of the mask according to

the invention with the seal provided by one chamber; and

Figure 2 is a view of the mask with the seal produced by the other chamber.

With reference to the above figures, the face or nose mask for non-invasive ventilation of patients in general, according to the invention, generally designated by the reference numeral 1, comprises a mask body 2 which has the conventional configuration of a face or nose mask and is provided with an inlet 3 for connection, by means of a hose 4, to a ventilation apparatus.

In the perimetric region, the mask has a flange 5 at which the sealing element for application to the face of the patient is provided.

The particularity of the invention is constituted by the fact that the sealing element is provided by at least one first chamber 10 and by at least one second chamber 11 which are advantageously arranged side by side, the first chamber being arranged outside with respect to the second chamber.

The chambers have separate connections to a source of pressurized air, and in particular there is provided a first connector 12 for the first chamber 10 and a second connector 13 for the second chamber 11; such connectors are connected to an inflation device which is constituted for example by extremely compact micropumps which can be actuated sequentially so as to release the pressure in one chamber and inflate the other chamber, thus ensuring the seal.

The inflation and deflation rate can be adjusted in any manner, since it is independent of the ventilator of the ventilation system.

In practice it is possible to alternate inflation and deflation with a period of a few seconds, consequently having the advantage that the skin is affected in the same region for a period which is substantially halved, but most of all with the advantage that in practice blood flow is never interrupted or hindered, thus preventing the occurrence of pain and dangerous sores.

In practice, the system adopted consists in removing pressure from one chamber and simultaneously restoring pressure in the other chamber, so that the seal is ensured at all times but the region where pressure is applied to the skin changes.

5 Advantageously, the chambers have a closed perimeter, but from the conceptual point of view there is no difference if the chambers 10, 11 affect only portions of the face and in any case the regions that are more severely affected by pain or sores, depending on the pressure applied in order to provide the seal.

10 From the above description it is thus evident that the invention achieves the intended aim and objects, and in particular the fact is stressed that a face mask is provided which has an inflatable sealing element which is entirely autonomous and independent of the ventilator used for ventilation, thus allowing to adjust the pressure inside the individual chambers independently
15 of each other and to provide alternating deflation and inflation of the chambers at a rate which can be adjusted at will in view of the fact that the chambers are separately connected to a source of pressurized air, for example constituted by micropumps.

20 The invention thus conceived is susceptible of numerous modifications and variations, all of which are within the scope of the inventive concept.

 All the details may also be replaced with other technically equivalent elements.

 In practice, the materials employed, as well as the contingent shapes and the dimensions, may be any according to requirements.

CLAIMS

1. A face or nose mask for non-invasive ventilation of patients in general, comprising a mask body provided with an inlet for connection to a ventilation apparatus and perimetrically provided with a sealing element for application to the face of a patient, characterized in that said sealing element comprises at least one first chamber and at least one second chamber which can be connected separately to a source of pressurized air.

2. The mask according to claim 1, characterized in that said first and second chambers have a closed perimeter.

3. The mask according to the preceding claims, characterized in that said first and second chambers lie side by side, one inside the other.

4. The mask according to one or more of the preceding claims, characterized in that said first and second chambers are alternately connected to said pressurized air source.

5. The mask according to one or more of the preceding claims, characterized in that said pressurized air source is constituted by micropumps, each of which is connected to the corresponding chamber.

FACE OR NOSE MASK FOR NON-INVASIVE VENTILATION OF
PATIENTS IN GENERAL

ABSTRACT OF THE DISCLOSURE

The face or nose mask (1) includes a mask body (2) with an inlet (3). The mask body (2) includes a sealing element with a first chamber (10), and a second chamber (11) which can be connected by connectors (12, 13) to a source of pressurized air.

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PCT/US00/06164

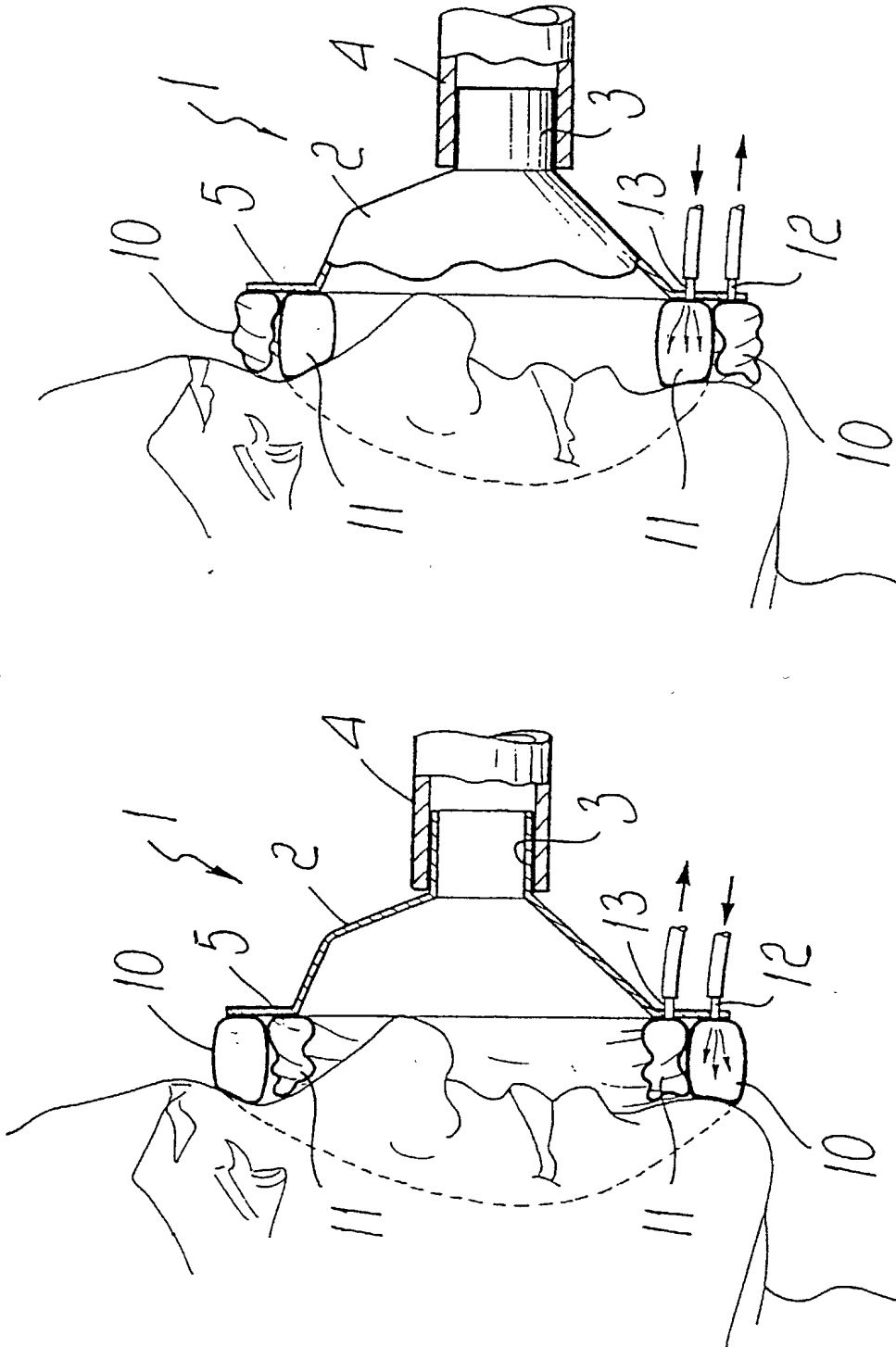


Fig. 2

Fig. 1

DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION

As the below named inventors, we hereby declare that:

Our residence, post office address and citizenship are as stated below next to our names,

We believe we are the original, first and joint inventors of the subject matter which is claimed and for which a patent is sought on the invention entitled FACE OR NOSE MASK FOR NON-INVASIVE VENTILATION OF PATIENTS IN GENERAL, the specification of which (check one)

 is attached hereto

X was filed on 9 March 2000 as PCT/US00/06164

United States Application Serial No. 10/018,899

and was amended on (or amended through) December 17, 2001
(if applicable)

We hereby state that we have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above.

We acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. § 1.56.

We hereby claim foreign priority benefits under 35 U.S.C. § 119 (a) - (d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

Priority Claimed

MI99A000521
Number

Italy

Country

12 March 1999

Day/Month/Year filed

X
Yes No

We hereby claim the benefit under 35 U.S.C. 119(e) of any United States

provisional application(s) listed below.

NONE

Appln. Serial No. Filing Date

We hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or § 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. § 112, we acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. § 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application.

<u>PCT/US00/06164</u>	<u>9 March 2000</u>	<u>expired</u>
Appln. Serial No.	Filing Date	Status
		(patented, pending, abandoned)

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

We hereby appoint the following attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

RICHARD A. BARDIN, Reg. No. 20,365; SAMUEL L. ALBERSTADT, Reg. No. 32,766; CRAIG B. BAILEY, Reg. No. 28,786; RICHARD B. CATES, Reg. No. 36,100; I. MORLEY DRUCKER, Reg. No. 19,751; PAUL Y. FENG, Reg. No. 35,510; JOHN K. FITZGERALD, Reg. No. 38,881; JOHN V. HANLEY, Reg. No. 38,171; JAMES JUO, Reg. No. 36,177; GILBERT G. KOVELMAN, Reg. No. 19,552; THOMAS H. MAJCHER, Reg. No. 31,119; JOHN S. NAGY, Reg. No. 30,664; DAVID G. PARKHURST, Reg. No. 29,422; JAMES W. PAUL, Reg. No. 29,967; RONALD E. PEREZ, Reg. No. 36,891; ELLSWORTH R. ROSTON, Reg. No. 16,310; THOMAS A. RUNK, Reg. No. 30,675; DAVID S. SARISKY, Reg. No. 41,288; and



Paula Bepko et al.

19 HOWARD N. SOMMERS, Reg. No. 24,138. Direct all telephone calls to James W. Paul, at telephone No. (310) 824-5555.

Address all correspondence to:

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Inventor's signature: [Signature]

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X Inventor's signature: [Signature]

Date: 15/03, 2002

Residence: Concordia (MO), Italy I+X

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41033 Concordi (MO)
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3-00
Full name of third inventor: Stefano NAVA

X Inventor's signature: [Signature]

Date: 15/03, 2002

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